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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORTUNA, ANA M

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

01/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/037,480	Applicant(s) CEVC ET AL.	
	Examiner Ana M. Fortuna	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,37,39 and 41 is/are rejected.
- 7) ☒ Claim(s) 38 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/05/07, 12/21/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

1. Claim 38 recites the limitation "solvent" in line 2. There is insufficient antecedent basis for this limitation on the claim.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 36, 37, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9009385 in view of Applicant's disclosure. This document teaches a composition including the penetrants and the amphiphilic compounds, e.g surfactants that can be selected from anionic, non ionic, amphoteric, etc (page 1, lines 1-30. The surfactants are detailed in Table 1 (page 16). The Percentages of the composition and the pH are further disclosed (page 3, lines 15-34; and page 4, line 20- page 8, line 15). The solubility of the composition is not disclosed, however, the surfactants suggested to be added to the composition correspond to the surfactants disclosed in the present invention (page 19, last paragraph-page 21). It would have been obvious to one skilled in this art at the time this invention was made to select a penetrants and a polar liquid, e.g. water, and a surfactant or mixture of surfactants from the list suggested in the WO reference above to achieve a composition as claimed in present claim 36. Applicant admits that forming a reservoir with the non-occlusive backing liner and an inner liner or membrane defining a reservoir for a composition

including a penetrant is known in the art (see specification, page 10, line 20-page 13, line 15). It would have been obvious to one skilled in this art at the time this invention was made to form a reservoir containing the composition to be transfer, e.g. to a skin, into a conventional patch, and further select the liner and membrane from the materials conventional in the art, such the lower liner or membrane allows the transfer of the composition to the skin in contact with the membrane, as patches or reservoir are admitted to be known for the purpose (as disclosed in the present specification).

2. Claims 36, 37, 39, 41 are rejected under 35 U.S.C. 103(a) as being obvious over Cevec (WO 00/44349) in view of applicant's admissions. This document ('349) discloses the composition of the present invention that is placed in the claimed patch (abstract, page 6, last paragraph- page 7, last line, and page 8, lines 9; page 14, lines 1 to line before last paragraph; page 15, second paragraph). the surfactants of amphiphilic substances are also disclosed (page 16 second paragraph through page 17, second paragraph). Formation of the composition into a patch is not disclosed. Applicant admits, as discussed in the paragraph above that patches containing transfersomes (r) or penetrants compositions are prepared within a reservoir defined by occlusive and non-occlusive liner or membrane that permeates the composition or the penetrants (see specification sections discussed above. It would have been obvious to one skilled in this art at the time this invention was made to alternatively select the contact or transfer of the composition via a conventional patch or reservoir material including a membrane.

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2). Document WO 00/44349 was assigned to US and published in English language and therefore has the effect as it was filed in the United States.

Allowable Subject Matter

3. Claims 38 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. The following is a statement of reasons for the indication of allowable subject matter: the liner with the vapor transmission rate as claimed in claim 38, and the backing liner with the claimed pore size range is not disclosed in the prior art of record for the patch or reservoir containing the specified composition.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 10/5/07 and 12/21/07 was filed after the mailing date of the a non-final on 4/11/07. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy is attached fro your records.

Conclusion

5. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/21/07, and 10/05/07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ana Fortuna/
Primary Examiner, Art Unit 1797

AF
January 5, 2008